

REMARKS/ARGUMENTS

Applicants have carefully reviewed the Office Action mailed on July 8, 2008. Applicants respectfully traverse all objections, rejections, and assertions made by the Examiner. Claims 1-25 are pending, with claims 22-25 having been withdrawn from consideration. The claims currently under examination are claims 1-21.

Claim Rejection(s) under 35 U.S.C § 103

On page 2 of the Office Action, claims 1-13 and 16-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacobson (U.S. Patent No. 4,545,374) in view of Ogawa et al. (U.S. Patent No. 5,976,146). This rejection is respectfully traversed. Claim 1 recites:

1. (PREVIOUSLY PRESENTED) A surgical instrument for accessing first and second pedicle locations of a spinal column, the surgical instrument comprising:
 - a) a portal member having an elongated aperture;
 - b) a blade member slidably positionable within the elongated aperture of the portal member, the blade member including a blade end; and
 - c) a placement wire having a first end positionable at one of the first and second pedicle locations, the blade member being slidably positionable over the placement wire with the placement wire received within at least a portion of the blade member;
 - d) wherein the elongated aperture of the portal member is sized to provide simultaneous access to each of the first and second pedicle locations when the blade member is removed from the elongated aperture of the portal member.

Jacobson does not appear to teach all of the elements of claim 1. In particular, Jacobson does not appear to teach at least the limitation “a blade member slidably positionable within the elongated aperture of the portal member, the blade member including a blade end . . .” The Examiner appears to state on page 2 of the Office Action that member 18 of the Jacobson device fulfills this limitation. (see Office Action, page 2 “a blade member (18, see also fig. 8) that is positionable along the aperture of the portal member with a blade-end . . .”). Applicants respectfully disagree with Examiner’s assertion.

As the Examiner is likely aware, “claims must be interpreted ‘in view of the specification’ without importing limitations from the specification into the claims unnecessarily.” *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (MPEP § 2106 I.C.). The specification for the invention herein claimed

clearly contemplates that the blade member cuts tissue. (see [0035] “As will be discussed in greater detail, the blade member 20 is used to provide an initial incision and the portal member provides access to the spinal column area through the incision.”) On the other hand, the Jacobson rongeur forceps 18 appears to scoop tissue. Member 18 of Jacobson is “a rongeur forceps 18, such as those shown in FIGS. 17-19, is inserted down the cannula 11 into the disc to scoop out the fragmented nucleus material . . . its jaws or scoops are opened to scoop up a portion of the fragmented material.” (see col. 7; lines 40-50, see also col. 8, lines 11-13). As a further indication that the rongeur forceps 18 of Jacobson do not cut or make incisions, Jacobson specifically teach “a knife 17 is inserted into the cannula 11 to cut a hole in the disc capsule...the knife is inserted through the capsule in order to fragment the nucleus cartilage-like material.” (see col. 7, lines 25-26 and 30-32). The rongeur forceps 18, therefore, appears to be a scoop not a “blade member” as is contemplated in claim 1.

In addition to Jacobson not teaching all of the elements of claim 1 that the Examiner asserts it does, Ogawa et al. do not appear to cure the failings of Jacobson. Neither Jacobson nor Ogawa et al. appear to teach the limitation of “the blade member being slidably positionable over the placement wire with the placement wire received within at least a portion of the blade member.” On pages 2 and 3 of the Office Action, the Examiner appears to state that Ogawa teaches this limitation:

“Ogawa et al. discloses . . . a guidewire (1) which goes through the guide device to assist in more precise targeting of the blade and entry into the spinal area. See also (Col. 11, lines 20-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Jacobson having at least a guidewire extending through the blade and nested dilators in view of Ogawa et al. to have improved access to the spinal area and improved precision during surgery.”

Applicants respectfully submit that the Examiner mischaracterizes the reference. The cited portion of the Ogawa et al. reference (Col. 11, lines 20-40) does not teach a “guide device to assist in more precise targeting of the *blade*.” (emphasis added). This excerpt does not describe a blade, but merely dilator 2 tubes 7 fitted onto the guidewire 1. (see Col. 11, lines 34-35: “The tube 7a having the smallest diameter is fitted on the guidewire 1.”) Guidewire 1 appears to be removed after the dilator tubes are placed, and, therefore, does not aid in more precise targeting of any blade: “Subsequently, the first tube 7a is fitted on the

inserted guidewire 1, and the distal end of the first tube 7a is inserted to the region P of surgical object of the tissue along the guidewire 1. Thereafter, the guidewire 1 is removed.” (Col. 13, lines 29-32).

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006):

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

Emphasis added; see page 14 of the April 30, 2007 decision. The Court further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

See page 14 of the April 30, 2007 decision. The Examiner has not provided reasoning with rational underpinning to support the conclusion of obviousness. The Examiner asserts that it would have been obvious “to construct the device of Jacobson having at least a guidewire extending through the blade and nested dilators in view of Ogawa et al. to have improved access to the spinal area and improved precision during surgery.” Applicants respectfully disagree. Jacobson appears to teach a cannula 30 having a tubular member 31 and anchor wires 33 slidably inserted into bores 34 defined by tubular member 31. See column 9, lines 17-19 and 41-47 and FIGS. 12-13. Jacobson teaches “anchor wires 33 which pierce the [the] disc capsule and prevent shearing movement between the disc and cannula.” See column 9, lines 43-45. Jacobson thus appears to teach wires 33 configured to anchor the cannula to a disc. As discussed above, Jacobson appears to teach a scooping device 18 that is inserted through the cannula after a blade is used to fragment disc nucleus material. See column 7, lines 40-50 and FIG. 8. Applicants submit that in view of Jacobson’s teaching of using wires to anchor a cannula to a disc and thereafter insert a scooping device to remove fragmented disc material, there is no rational reasoning for modifying the device to somehow have a guidewire extending through the scooping device to improve access to the spinal area, as the Examiner appears to assert. Further, if the Examiner is considering the knife 17 of Jacobson to be the claimed blade, there is also no rational reasoning for modifying the knife to have a

guidewire extending through it to somehow "have improved access to the spinal area and improved precision during surgery" as asserted by the Examiner. MPEP 2143.01 III states:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless **>the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007)

Applicants submit that somehow constructing the knife 17 or scooping rongeur 18 of Jacobson to have a guidewire extending through the blade would not have provided predictable results to one of ordinary skill in the art. The Examiner appears to be relying on the fact that Jacobson and Ogawa et al. could be combined in some fashion, without providing the necessary rational reasoning for an obviousness rejection. The rejection is thus in error. Reconsideration and withdrawal of the rejection are respectfully requested.

For at least the foregoing reasons, Applicants respectfully submit that Jacobson does not teach the elements of claim 1 the Examiner asserts that it does, nor does it teach each and every element of claim 1. Ogawa et al. do not cure the failings of Jacobson. Applicants, therefore, believe that claim 1 is patentable over Jacobson in view of Ogawa et al. Withdrawal of the rejection is respectfully requested.

Regarding claims 2-13, claim 2 recites:

2. (PREVIOUSLY PRESENTED) A surgical instrument for providing an access opening to spinal column area, the surgical instrument comprising:
 - a) a first wire and a second wire for locating an access opening site;
 - b) an incremental opening arrangement having a plurality of nested members, the plurality of nested members including at least:
 - i) a dissector member slidably positionable over the first and second wires with the first and second wires being received within at least a portion of the dissector member, the first dissector member configured to provide an access opening at the access opening site;
 - ii) a sleeve member slidably positionable over the dissector member, the sleeve member being sized and configured to expand the opening area of the access opening at the access opening site.

Jacobson does not appear to teach each and every element of claim 2 and Ogawa et al. do not appear to cure the failings of Jacobson for reasons similar to those stated above regarding claim 1. As stated by the Examiner on page 2 of the Office Action, Jacobson does not teach "a

layered, nested incremental portal assembly in the device and also wherein the placement wire is relocated to be within part of the blade." The Examiner states on pages 2 to 3 of the Office Action that "Ogawa et al. discloses device to assist in accessing a surgical site having nested, tube-like guides (Fig. 1A, and 8a-d) . . ." Even assuming, for the sake of argument, that the tubes 7a-7d constitute "the plurality of nested members," they do not include a dissector member that is slidably positionable over the first and second wires (with both wires being received within at least a portion of the dissector member) and is configured to provide an access opening. Also, they do not include a sleeve member that is slidably positionable over the dissector member. MPEP 2143.03 states:

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Neither Jacobson nor Ogawa et al. appear to show the elements contained in claim 2. Additionally, the Examiner has not provided rational reasoning as to why one of ordinary skill in the art would have been motivated to modify Jacobson and/or Ogawa et al. to achieve the claimed structure. For at least the foregoing reasons, Applicants believe that claim 2 is patentable over Jacobson in view of Ogawa et al. As claims 3-13 depend from claim 2 and include additional limitations, they are also believed patentable over Jacobson in view of Ogawa et al. Withdrawal of the rejection is respectfully requested.

Regarding claims 16-21, claim 16 recites:

16. (PREVIOUSLY PRESENTED) A surgical instrument for accessing first and second pedicle locations of a spinal column, the surgical instrument comprising:
- a) at least a first guide wire having a first end selectively positionable at one of the first and second pedicle locations;
 - b) a nested arrangement slidably positionable over the first guide wire, the nested arrangement including at least:
 - i) a blade member slidably positioned over the first wire with the first wire received within at least a portion of the blade member, the blade member including a blade end configured to provide an incisional opening; and
 - ii) an outer portal member configured to slide over the blade member for introduction into the incisional opening, the outer portal member

having an elongated access aperture, the elongated aperture having a longitudinal dimension that corresponds to the distance between the first and second pedicle locations.

For at least reasons similar to those stated above regarding claims 1 and 2, claim 16 is believed patentable over Jacobson in view of Ogawa et al. As claim 17-21 depend from claim 16 and include additional limitations, they are also believed patentable over Jacobson in view of Ogawa et al. Withdrawal of the rejection is respectfully requested.

On page 3 of the Office Action, claims 14-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacobson (U.S. Patent No. 4,545,374) and Ogawa et al.(U.S. Patent No. 5,976,146) and further in view of Koros et al. (U.S. Patent No. 5,928,139). This rejection is respectfully traversed. Claims 14-15 depend from claim 2. As mentioned above, claim 2 is believed patentable over Jacobson in view of Ogawa et al. Koros et al. do not appear to cure the failings of Jacobson in view of Ogawa et al. Applicants, therefore, believe that claim 2 is patentable over the combination of Jacobson and Ogawa et al. in further view of Koros et al. As claims 14-15 depend from claim 2 and include additional limitations, they are also believed patentable over the cited art. Withdrawal of the rejection is respectfully requested.

CONCLUSION

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their attorney,

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